

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II)  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

Date of mailing (day/month/year)  
27 April 2006 (27.04.2006)

To:

STERNAGEL, FLEISCHER, GODEMEYER & PARTNER  
Braunsberger Feld 29 Sternagel, Fleischer,  
51429 Bergisch Gladbach Godemeyer & Partner  
ALLEMAGNE

04. Mai 2006

eingegangen/received

Applicant's or agent's file reference  
P11658WO

**IMPORTANT NOTIFICATION**

International application No.  
PCT/EP2004/004587

International filing date (day/month/year)  
30 April 2004 (30.04.2004)

Applicant

MHM HARZBECHER MEDIZINTECHNIK GMBH et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yolaine Cussac

Facsimile No.+41 22 740 14 35

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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>P11658WO</b>	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. <b>PCT/EP2004/004587</b>	International filing date ( <i>day/month/year</i> ) <b>30 April 2004 (30.04.2004)</b>	Priority date ( <i>day/month/year</i> ) <b>09 May 2003 (09.05.2003)</b>	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant <b>MHM HARZBECHER MEDIZINTECHNIK GMBH</b>			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 11 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input checked="" type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report <b>18 April 2006 (18.04.2006)</b>	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Authorized officer  <b>Yolaine Cussac</b> Telephone No. +41 22 338 70 80

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>P11658WO</b>		Date of mailing (day/month/year)
		FOR FURTHER ACTION See paragraph 2 below
International application No. <b>PCT/EP2004/004587</b>	International filing date (day/month/year) <b>30.04.2004</b>	Priority date (day/month/year) <b>09.05.2003</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>MHM HARZBECHER MEDIZINTECHNIK GMBH</b>		

**1. This opinion contains indications relating to the following items:**

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/20.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

Translation

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material
    - in written format
    - in computer readable form
  - c. time of filing/furnishing
    - contained in the international application as filed.
    - filed together with the international application in computer readable form.
    - furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II Priority

1.  The following document has not yet been furnished:

copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).  
 translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application  
 claims Nos. 21, 22

because:

the said international application, or the said claims Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. 21, 22 \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. \_\_\_\_\_

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																												
<p><b>1. Statement</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Novelty (N)</td> <td style="width: 60%;">Claims</td> <td style="width: 20%; text-align: right;">YES</td> </tr> <tr> <td></td> <td>1-20</td> <td></td> </tr> <tr> <td></td> <td>Claims _____</td> <td>NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td>1-12, 14-20</td> <td></td> </tr> <tr> <td></td> <td>Claims</td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td>1-20</td> <td></td> </tr> <tr> <td></td> <td>Claims _____</td> <td>NO</td> </tr> </table> <p><b>2. Citations and explanations:</b></p> <p><b>2. Novelty</b></p> <p>Reference is made to the following documents:</p> <p><b>D1:</b> WO 02/03854 A2  <b>D2:</b> US 4,617,608  <b>D3:</b> WO 2004/024300 A1  <b>D4:</b> US 6,193,864 B1</p> <p>2.1 The international application <b>D3</b> published on 25 March 2004 claims priority of 11 September 2002. Its content includes a device with a measuring chamber (700) through which blood can flow, with a fixed housing wall (10) and a membrane (201), i.e. a flexible wall, with electrodes on these two walls, which would be suitable for use according to the application (see page 30, line 20 to page 31, line 20) and therefore relates to the subject matter of the present application.</p> <p>2.2 <b>Claim 1.</b> (1) <b>D1</b> is considered the closest prior art to the subject matter of claim 1. It discloses a device for measuring the pressure of a medium (see claims 1 and</p>			Novelty (N)	Claims	YES		1-20			Claims _____	NO	Inventive step (IS)	Claims	YES		1-12, 14-20			Claims	NO	Industrial applicability (IA)	Claims	YES		1-20			Claims _____	NO
Novelty (N)	Claims	YES																											
	1-20																												
	Claims _____	NO																											
Inventive step (IS)	Claims	YES																											
	1-12, 14-20																												
	Claims	NO																											
Industrial applicability (IA)	Claims	YES																											
	1-20																												
	Claims _____	NO																											

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<p>11), the device comprising a measuring chamber (7), through which the medium can flow and which has at least one elastically deformable wall (membrane 11), at least one wall (the remaining part 15) that is more rigid in comparison to said first wall, and an inlet and outlet for the medium (attachments 2 and 3 in figure 1a). Therefore, the first special technical feature explicitly differing from the prior art, from claim 1, is two electrodes (30, 32).</p> <p>(2) <b>D1</b> does not disclose any electrodes in or on the walls of the measuring chamber. Therefore, the subject matter of claim 1 is novel (within the meaning of PCT Article 33(2)).</p> <p><b>3. Inventive step</b></p> <p>3.1. <b>Claim 1.</b> (1) The electrodes (30, 32) are used for measuring pressure (see application, page 13, line 30 to page 14, line 1), by means of the measurement of the capacitive impedance between the walls (the application implies this, page 6, lines 9 to 15).</p> <p>(2) <b>D2</b> discloses a device for measuring pressure, namely a pressure sensor with two electrodes (11, 14) which are mounted on a fixed wall (12) and on a flexible membrane (see <b>D2</b>, page 2, line 62 to page 3, line 33) and are used for capacitive pressure measurement (see <b>D2</b>, page 1, lines 15-24). A person skilled in the art would be able to use this device from <b>D2</b> as the transducer 12 in <b>D1</b> (see <b>D1</b>, page 21, line 12). However, in the device thus obtained, the electrodes are placed on the walls of the</p>	

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

pressure sensor/transducer (12) and not on the walls of the measuring chamber/pressure dome (1, see **D1**, figures 1 and 3).

Therefore, the subject matter of claim 1 involves an inventive step (within the meaning of PCT Article 33(3)).

3.2. Claims 2-12 and 14-20 are dependent on claim 1 and therefore also meet the PCT requirements for novelty and inventive step.

3.3 **Claims 13 and 14 (dependent on 13)**. (1) **D1** discloses a device according to the preamble of claim 1 (see section 2.2 of this expert opinion), but not two electrodes (30, 34) for measuring conductivity and hence the hematocrit value (see application, page 15, line 29 to page 16, line 15).

(2) **D4** discloses a sensor with two electrodes (403c, 403d) for determination of the hematocrit value (see **D4**, column 12, lines 64-65, and column 13, lines 24-25). Therefore, if a person skilled in the art wanted to determine the hematocrit value in **D1**, he would obviously use this hematocrit sensor with electrodes on a non-flexible alumina substrate (see **D4**, column 11, lines 55-59) in **D1**.

Therefore, the subject matter of claims 13 and 14 does not involve an inventive step (within the meaning of PCT Article 33(3)) and the requirements of PCT Article 33(1) are not met.

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<p>3.4. <b>Claims 15-20 (dependent on 13).</b> For coupling the pressure sensors in D2 to the AC voltage exciter, a person skilled in the art would obviously use connector pins, and the pins would be held by the AC voltage exciter, as a result of which it is a retaining device.</p> <p>Conventional electrical connectors are provided with concealed contact surfaces and surrounding collar parts. (Solutions for) false contacting are widely known. It is always possible to define a part which is in one piece.</p> <p>D2 discloses spraying the chrome electrode in a thermal vapor-deposition method (see D2, column 5, line 37). D1 discloses a protective cap, namely the housing (10) with a base part and an edge with hooks (13) and/or the housing of the transducer (12) in figure 3 which protect the membrane (see D1, figure 3).</p> <p>Therefore, the subject matter of claims 15-20, dependent on claim 13, does not involve an inventive step (within the meaning of PCT Article 33(3)), and the requirements of PCT Article 33(1) are not met.</p>	

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**4. Clarity**

**4.1. All claims.** Where the claims use expressions such as "more particularly ..." "and/or ...", or "or ...", it is not clear which of the possibilities are being claimed. The corresponding optional passages have not been taken into consideration in this expert opinion. This lack of clarity means that the requirements of PCT Article 6 are not met.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient,

Continuation of:

Box III

**1. Subject matter according to PCT Article 34(4)(a)(i)**

**1.1 Claims 21 and 22.** The method claim 21 mentions "determination of the hematocrit value" where "blood flows through the measuring chamber in an extracorporeal circuit", which in the context of the invention, relating to "dialysis and other medical applications" (see page 3, lines 27-28), is to be understood as a method, and where the hematocrit value of a subject is determined, i.e. a method for diagnosis of the subject.

Therefore, claims 21 and 22 define a method for treatment of the human or animal body by surgery or therapy and/or a diagnostic method practised on the human or animal body (PCT Rule 67.1(iv)), and no expert opinion has been established in respect of the novelty, inventive step and industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).